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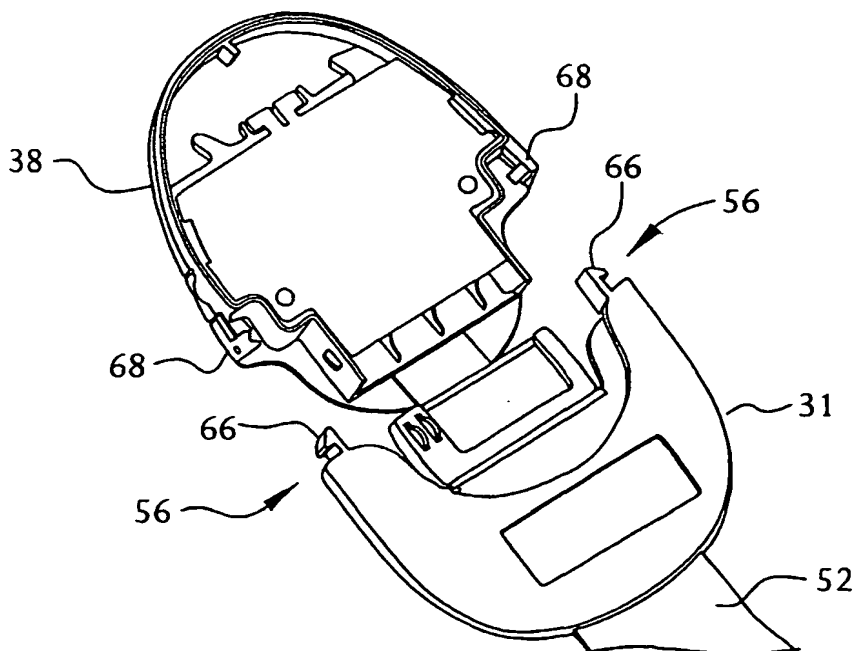
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(54) Title: **DISPOSABLE VITAL SIGNS MONITORING SENSOR BAND WITH REUSABLE ELECTRONICS MODULE**



(57) Abstract: A cordless, disposable sensor band containing sensors for acquiring physiological parameters from a patient characterized by a reusable electronics circuit that is connected to each disposable sensor band via a two part housing connected together by an easy to use clip mechanism. The first part of the housing contains disposable batteries and is connected to the sensor assembly via sensor tracks. The first part of the housing is typically disposed with the disposable sensor band after use. The second part of the housing, on the other hand, contains the reusable electronics circuit and is clipped to the first part of the housing to activate the sensor band. Once the housing parts are connected, the electronics are powered by the batteries in the first part of the housing.

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DISPOSABLE VITAL SIGNS MONITORING SENSOR BAND WITH REUSABLE ELECTRONICS MODULE

BACKGROUND OF THE INVENTION

5 Field of the Invention

The present invention relates to a disposable vital signs monitoring sensor band for use in a system that monitors vital signs and captures data from a patient remotely using telemonitoring techniques. In particular, the present invention is a disposable vital signs monitoring sensor band with a reusable electronics module that connects to the
10 sensor band to enable the remote electronic capture of noninvasive vital signs data including, *e.g.*, full waveform ECG, respiration rate, blood oxygenation, and the like.

Description of the Prior Art

Remote patient monitoring techniques are generally known in which electrodes are
15 placed on the patient to monitor the patient's vital signs and the captured data is transmitted to a remote display for monitoring the patient's condition. Remote monitoring systems are known which permit a doctor or nurse to monitor the conditions of several hospitalized patients from a central monitoring site in the hospital. Typically, sophisticated patient monitoring equipment is used to collect data from the patient, and
20 the collected data is transmitted via wire to the central monitoring site in the hospital. Generally, wireless systems are problematic in the hospital setting because of the proximity of the respective patients and the amount of interference found in such a setting.

Remote monitoring of patients' vital signs from their homes introduces an entirely new
25 set of challenges for transmitting the gathered data to a central location for evaluation. Numerous attempts have been made to facilitate such data collection and transmission; however, in each case, cumbersome and uncomfortable monitoring equipment is placed on the patient and the patient is tethered to the monitoring equipment by electrical cords, thereby limiting the patient's movement. In some prior art systems, the electrical
30 cords have been removed and the transmissions to the monitoring equipment made

using telemetry techniques. Unfortunately, such systems limit the movement of the patient to a limited area near the vital signs monitor.

On the other hand, Bornn et al. describe a portable physiological data monitoring/alert system in U.S. Patent Nos. 4,784,162; 4,827,943; 5,214,939; 5,348,008; 5,353,793; and
5 5,564,429 in which one or more patients wear sensor harnesses including a microprocessor which detects potentially life-threatening events and automatically calls a central base station via radiotelemetry using a radio modem link. In a home or alternate site configuration, communications between the base station and remote unit is by way of commercial telephone lines. Generally, the system automatically calls A911"
10 or a similar emergency response service when an abnormality is detected by the ECG monitor. Unfortunately, the sensor harness is quite cumbersome and conspicuous and uncomfortable for the patient.

Segalowitz discloses a wireless vital signs monitoring system in U.S. Patent Nos. 4,981,141; 5,168,874; 5,307,818; and 5,511,553 including a precordial strip patch
15 having a multi-layer flexible structure for telemetering data by radio frequency or single wire to hardware recording apparatus and a display monitor. Microsensors and conductive contact elements (CCEs) are mounted on the strip patch so as to permit simultaneous and continuous detection, processing and transmission of 12-lead ECG, cardiac output, respiration rate, peripheral blood oximetry, temperature of the patient,
20 and ECG fetal heart monitoring via a single wavelength of radio frequency transmission. While the precordial strip patch used by Segalowitz purportedly transmits vital signs data up to 50 meters, it requires a dual-stage operational amplifier chip, an encoder modulator chip, a wireless transmitter chip including an oscillator, and other costly components such as artificial intelligence software, sound and visual
25 alarms, and a microprocessor. As a result, the precordial strip patch is relatively expensive to manufacture and operate. Also, as with the other telemetry systems noted above, the emphasis of Segalowitz is on real-time monitoring and alerting of medical personnel to immediate medical needs of the patient.

Platt et al. also disclose a sensor patch for wireless physiological monitoring of patients
30 in U.S. Patent No. 5,634,468. Platt et al. describe a sensor and system for monitoring ECG signals remotely from patients located in non-hospital sites. In this system, a sensor patch containing sensing electrodes, signal processing circuitry and radio or

infra-red transmission circuitry is attached to the patient's body and preferably worn for at least a week before its power supply is exhausted and the sensor patch is thrown away. A receiver at a primary site in the vicinity of the patient receives the data transmitted by the sensor patch and stores the sensed data. When the patient feels
5 discomfort or concern, or if the portable unit sounds an alarm, the patient telephones the monitoring station and downloads the stored data from the portable unit via the standard voice telecommunications network. The downloaded ECG data is then monitored and analyzed at the monitoring station. The receiver in the proximity of the patient may be a portable unit carried around by the patient, where the portable unit
10 includes a receiver, a processor for processing the received data to identify abnormalities, a memory for storing the sensed data, and circuitry for interfacing to a telephone line to send the ECG data signals to the monitoring station. The monitoring station decodes the received ECG signals and performs beat and rhythm analysis for classification of the ECG data. If an abnormal condition is discovered, medical
15 personnel in the vicinity of the patient are contacted.

In commonly owned U.S. Patent Application Serial Numbers 09/292,405, 09/292,159, 09/292,157, and 09/591,597, the contents of which are incorporated herein in their entireties, a remote telemonitoring system and associated disposable sensor band are described for use to continuously collect vital signs data from a patient without
20 interaction with medical personnel. In the system described therein, the electronics of the disposable sensor band are typically thrown away with the sensor band, although a reusable memory card was disclosed for use in collecting the data. It has been found that the cost of the disposable sensor band would be significantly reduced if the electronics of the sensor band were designed to be reusable. The present invention has
25 been designed to address this need in the art.

SUMMARY OF THE INVENTION

The present invention meets the above-mentioned need in the prior art by providing a reusable electronics circuit that is connected to each disposable sensor band via a two
30 part housing connected together by an easy to use clip mechanism. The first part of the housing contains disposable batteries and is connected to the sensor assembly via sensor tracks. The first part of the housing is typically disposed with the disposable

sensor band. The second part of the housing, on the other hand, contains the reusable electronics and is clipped to the first part of the housing to activate the sensor band. Once the housing parts are connected, the electronics are powered by the batteries in the first part of the housing.

- 5 The invention is an adhesive, cordless, disposable sensor band with electrode patches, other sensors, circuit traces, and an electronics unit referred to herein as an "epatch" that collects, stores, and/or transmits detected vital signs data. The sensor band is easy-to-use and is positioned on the patient by the patient. The sensor band is designed to be worn comfortably by the patient for 24 hours, at which time the sensor band may
- 10 be discarded and replaced by a new sensor band. The epatch is ideally designed to store and/or transmit all vital signs data generated by the patient during that 24 hour period to a personal data logger located on or near the patient. The epatch has a first part that is connected to the circuit traces on the disposable sensor band and that contains the batteries for the electronics circuit as well as a clip mechanism with latches for
- 15 engaging and releasing counterpart latches of the second part of the epatch. The second part of the epatch contains the reusable electronics unit that is activated when plugged into the first part of the epatch via a corresponding latch. After use, the second part of the epatch is removed from the sensor band before the sensor band is discarded. The electronics circuitry is then reused with other sensor bands, as needed.

20

BRIEF DESCRIPTION OF THE DRAWINGS

- The above and other objects and advantages of the invention will become more apparent and more readily appreciated from the following detailed description of a presently preferred exemplary embodiment of the invention taken in conjunction with the
- 25 accompanying drawings of which:

FIGURE 1 is a general block diagram of a disposable sensor band in accordance with the invention.

- FIGURE 2(a) illustrates the top side of the sensor band (away from the patient's skin) including electrodes for attachment to the patient's body for measuring vital signs data
- 30 such as full waveform single or multiple lead ECG, full waveform chest respiration, and blood oxygen levels using the techniques of the invention.

FIGURE 2(b) illustrates the back side of the sensor band (towards the patient's skin) of FIGURE 2(a) including electrodes for attachment to the patient's body for measuring vital signs data such as full waveform single or multiple lead ECG, full waveform chest respiration, and blood oxygen levels using the techniques of the invention.

5 FIGURE 3 illustrates an exploded view of the reusable electronics module of the invention.

FIGURE 4 illustrates a top plan view of the reusable electronics module when the two halves of the housing are connected.

FIGURE 5 illustrates the reusable electronics module separated into its two portions so
10 as to show the contact areas on the respective portions.

FIGURE 6 illustrates the view of FIGURE 5 with the battery cover removed.

FIGURE 7 illustrates the view of FIGURE 6 with the two portions of the electronics unit clipped together.

15 DETAILED DESCRIPTION OF PRESENTLY PREFERRED EMBODIMENTS

A system and method with the above-mentioned beneficial features in accordance with a presently preferred exemplary embodiment of the invention will be described below with reference to FIGURES 1-7. It will be appreciated by those of ordinary skill in the art that the description given herein with respect to those figures is for exemplary
20 purposes only and is not intended in any way to limit the scope of the invention. All questions regarding the scope of the invention may be resolved by referring to the appended claims.

As described in detail in the aforementioned commonly owned U.S. Patent Application Serial Numbers 09/292,405, 09/292,159, 09/292,157, and 09/591,597, the disposable
25 sensor band is designed to extend across the patient's chest and includes electrodes and other sensors which are situated so as to measure full waveform single or multiple lead ECG, full waveform chest respiration (using impedance and/or resistance bend sensor), and perhaps other physiological parameters such as skin temperature and motion. Of course, other vital signs, such as EEG and blood oxygenation (SpO_2), could be
30 measured as desired using sensors included within the existing sensor band and placed either on the chest or elsewhere on the body, or using sensors in another sensor band placed either on the chest or elsewhere on the patient's body. Conventional blood

oxygenation sensors placed on the finger, wrist, or ear may also provide data through a wire or wireless link to the sensor band. Signal processing circuitry of the sensor band receives the sensor data and is powered by, *e.g.*, an alkaline battery pack to permit the sensor band to collect vital signs data for approximately 30 hours and to store the collected vital signs data in the epatch and/or to transmit the data to a personal data logger of the type described in U.S. Patent Application Serial Numbers 09/292,158 or 09/590,996, the contents of which are hereby incorporated by reference in their entireties, that may be carried by the patient or located nearby. The sensor band is typically removed and disposed of every 24 hours and replaced by a new sensor band.

As will be explained in more detail below, the sensor band is designed such that the sensor electronics of the sensor band are included in a reusable electronics module, referred to herein alternatively as an "epatch." In a preferred embodiment, the epatch has a two part housing: a first housing part, or "clip," that is attached to the disposable sensor band and disposed therewith, and a second housing part that contains the actual electronics circuitry and is connected to the clip for activation of the sensor band. In the preferred embodiment, the batteries for the epatch are included in the disposable clip portion so that the patients do not have to handle batteries and a new sensor band can be assured of having enough power to last for a 24 hour session. This design also enables the reusable housing portion to be kept small in size and light in weight.

FIGURE 1 is a general block diagram of a disposable sensor band 10 in accordance with the invention. As shown, the sensor band 10 in a preferred embodiment includes a disposable on-body sensor portion 12 connected via interconnect 14 to a reusable electronics portion ("epatch") 16. As shown, on-body sensor 12 includes electrodes 18 connected by circuit traces 20 and a power source 22 that powers the electronics of epatch 16 when the epatch is connected to the on-body sensor 12 via interconnect 14. Epatch 16 includes signal processing circuitry 24 that receives, amplifies, filters, processes the analog data from the sensors 18, performs analog to digital data conversion at 10 bit accuracy (with subsequent reduction for all but the ECG signal), and the like, and a microcontroller 26 that formats the data stream from the signal processing circuitry 24 for transmission via radio transmitter 28 to a personal data logger or other mechanism for storing the vital signs data. Of course, the functionality of the signal processing circuitry 24 and the micro-controller 26 may be performed by

one or more ASICs or by one or more micro-controllers using techniques known in the art. As shown, an SpO₂ monitoring device 30 including an ear clip or finger sensor also may provide SpO₂ data to the epatch 16 for transmission using techniques known in the art. In accordance with the invention, the interconnect 14 and power source 22 are including in a first housing portion or "clip" that connects to a second housing portion containing the epatch 16 with its electronics circuits 24, 26, and 28. More details concerning the design and manufacture of the sensor band 10 can be found U.S. Patent Application Serial Nos. 09/292,159 and 09/292,157.

The disposable sensor band 10 of the invention thus includes on-body sensor 12 and an electronics unit or "epatch" 16 that are jointly responsible for the collection of the required physiological parameters and broadcast of the collected data to a personal data logger or other monitoring device. The epatch 16, on the other hand, processes the ECG, respiration, and SpO₂ data and encodes the data into digital form. In a preferred embodiment, an identifier is attached to the data to identify the source of the data prior to transmission of packetized data using a unidirectional UHF radio link provided by radio transmission circuitry 28. Preferably, the epatch 16 is easy to connect to the on-body sensor 12 using interconnect 14 comprising clip portion 31 for accepting the housing of epatch 16 in a latch fit. Once connected to the clip portion 31, the epatch 16 preferably performs self-testing on power up and transmits the result to verify proper operation. More detail regarding the interconnection between the epatch 16 and the on-body sensor 12 will be provided below.

FIGURE 2(a) illustrates the top side of the disposable sensor band 10 (away from the patient's skin) with the membrane 32 partially removed to permit the circuit traces 20 to be seen. Figure 2(a) further illustrates electrodes 18 for attachment to the patient's body for measuring vital signs data such as full waveform single or multiple lead ECG or full waveform chest respiration using the techniques of the invention, while FIGURE 2(b) illustrates the back side of the disposable sensor band 10 (towards the patient's skin). In accordance with the invention, the sensors 18 are placed in the appropriate precordial positions for measuring the desired physiological parameters such as ECG data. Since the spacing between the precordial positions may vary for patients depending upon size, the disposable sensor band 10 preferably comes in a range of sizes to accommodate patients of different sizes.

The sensor band 10 shown in FIGURES 2(a) and 2(b) comprises a 3 layer construction including a breathable membrane 32, screen printed polyester 34, and hydrogel disks 36 placed over electrodes 18. The polyester 34 has the tracks 20 and electrodes 18 screen printed onto its surface, and the tracks 20 are covered with a skin-friendly dielectric and insulating material layer that prevents moisture from affecting the electrical properties of the circuitry and prevents the polyester from causing any irritation to the patient. Circular hydrogel disks 36 are placed on each electrode 18 to provide electrical continuity between the patient's skin and the electrode 18. Both the polyester 34 and the hydrogel disks 36 are pre-cut into their shapes before the final construction stage. During the final construction stage, the polyester 34 and hydrogel disks 36 are sandwiched between the breathable membrane 32 and a topside release liner preferably of the type described in commonly owned copending U.S. Patent Application Serial No.

(Attorney Docket No. NEXT-0029), the contents of which are incorporated herein by reference. The adhesive surface of the membrane 32 is used to attach the electrodes 18 to the patient's skin and to hold the polyester 34 in position. The membrane 32 is cut to shape, leaving the release liner on the skin side the same shape as the sensor 18. To help during the construction process, the polyester 34 has tabs and two or more alignment holes to help position the polyester 34 on the release liner on the skin side and to locate the final cut.

FIGURE 3 illustrates an exploded component view of a preferred embodiment of the electronics unit ("epatch") housing in accordance with the invention. As shown, the epatch housing preferably includes a clip portion 31 that is disposed on the on-body sensor and disposable therewith after use, and a reusable electronics housing portion 38. Electronics housing portion 38 includes a bottom case portion 40, a PCB 42 containing the sensor electronics including transmission antenna 44, a connector 46, and a top case portion 48. The clip portion 31, on the other hand, includes bottom case portion 50, a flexible track strip 52 for connection to the tracks 20 of the on-body sensor 12, a top case portion 54 including latch mechanism 56, a sealing gasket 58, battery contacts 60, battery spring 62, and batteries 64. FIGURE 4 illustrates a plan view of the epatch when the clip portion 31 and reusable electronics housing portion 38 are connected.

FIGURE 5 illustrates the epatch separated into the clip portion 31 and the reusable electronics housing 38 so as to show the latch mechanism 56 in more detail. As

illustrated, the clip portion 31 includes latches 66 that engage counterpart latches 68 of the reusable electronics housing 38. Once the housing parts are connected, a connection is also made between the track strip 52 and the connector 46 so as to facilitate circuit connection between the electrodes 18 and batteries 64 and the electronics circuitry on the PCB 42. FIGURE 6 illustrates the view of FIGURE 5 with the bottom case portion 50 removed to expose the batteries 64. FIGURE 7 illustrates the view of FIGURE 6 with the clip portion 31 and the reusable electronics housing 38 clipped together such that latches 66 and 68 engage each other. The reusable electronics housing 38 may be readily disengaged from clip portion 31 by squeezing the clip portion 31 at arrows "A". Such an engage and release mechanism is desirable since it is simple and easy to use by patients who are not particularly dexterous.

Although an exemplary embodiment of the invention has been described in detail above, those skilled in the art will readily appreciate that many additional modifications are possible in the exemplary embodiment without materially departing from the novel teachings and advantages of the invention. For example, the batteries may be included in the reusable portion of the patch and different types of latch mechanisms and connector mechanisms may be used. Also, the housing may have any desirable size and shape, although a proprietary connector and/or housing design is desired to prevent third parties from connecting other unapproved and untested circuitry to the outputs of the electrodes of the sensor band. All such modifications are intended to be included within the scope of this invention as defined in the following claims.

Claims

1. A sensor band for application to a patient's skin, comprising:
a membrane having at least one sensor mounted thereon for application to a
predetermined position on the patient's skin for detecting at least one physiological
parameter, a circuit trace formed on said membrane, and a clip connected to said circuit
trace; and
an electronics housing adapted to engage with said clip so as to connect said at least one
sensor to electronics circuitry in said electronics housing via said circuit trace.

10

2. A sensor band as in claim 1, wherein said clip comprises a battery case and
batteries that provide power to said electronics circuitry.

15

3. A sensor band as in claim 1 or 2, wherein said electronics circuitry processes
physiological parameter signals from said at least one sensor for at least one of storage
and transmission to a monitoring location.

20

4. A sensor band as in claim 1, 2 or 3, wherein said electronics housing comprises
a connector that connects said electronics circuitry to said circuit trace.

5. A sensor band as in any proceeding claim, wherein said clip and said
electronics housing each comprise latch mechanisms arranged to engage each other to
connect said electronics housing to said membrane via said clip.

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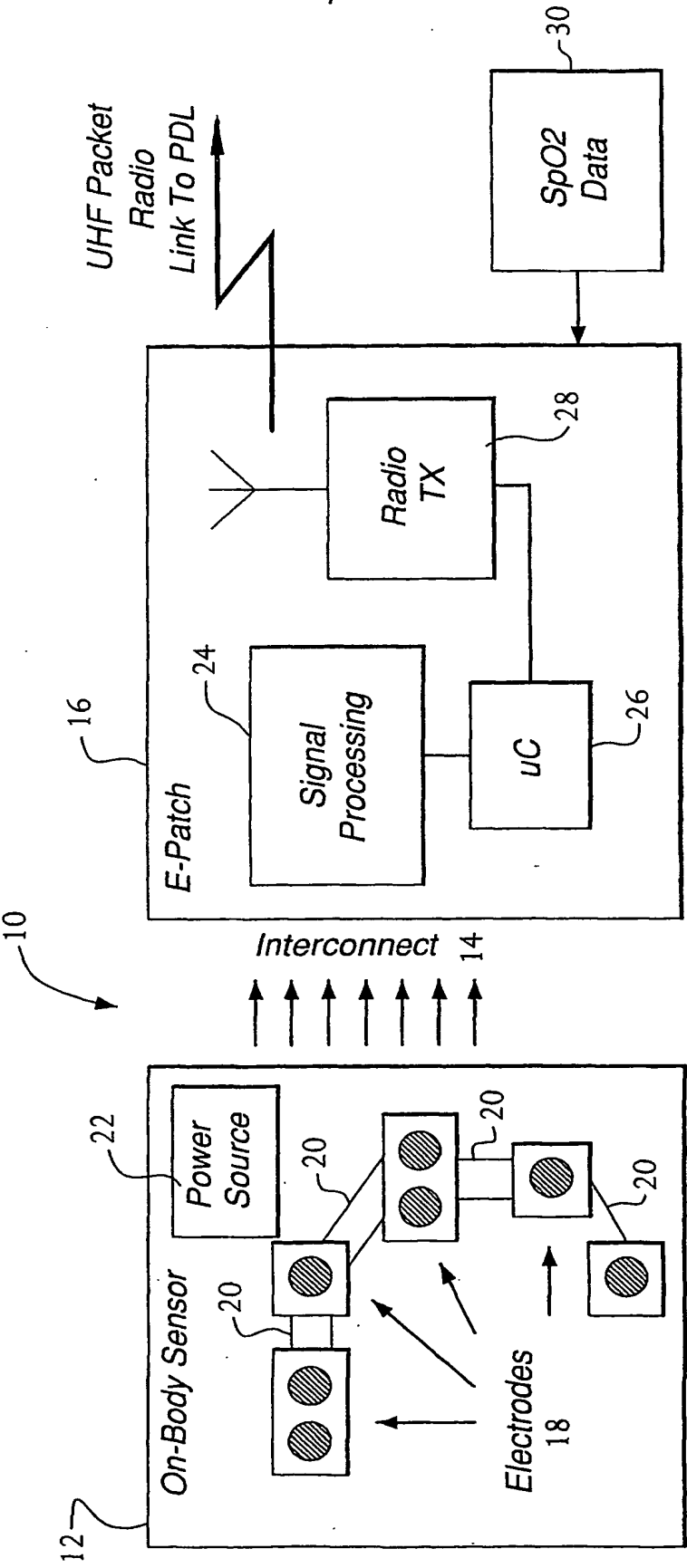


FIG. 1

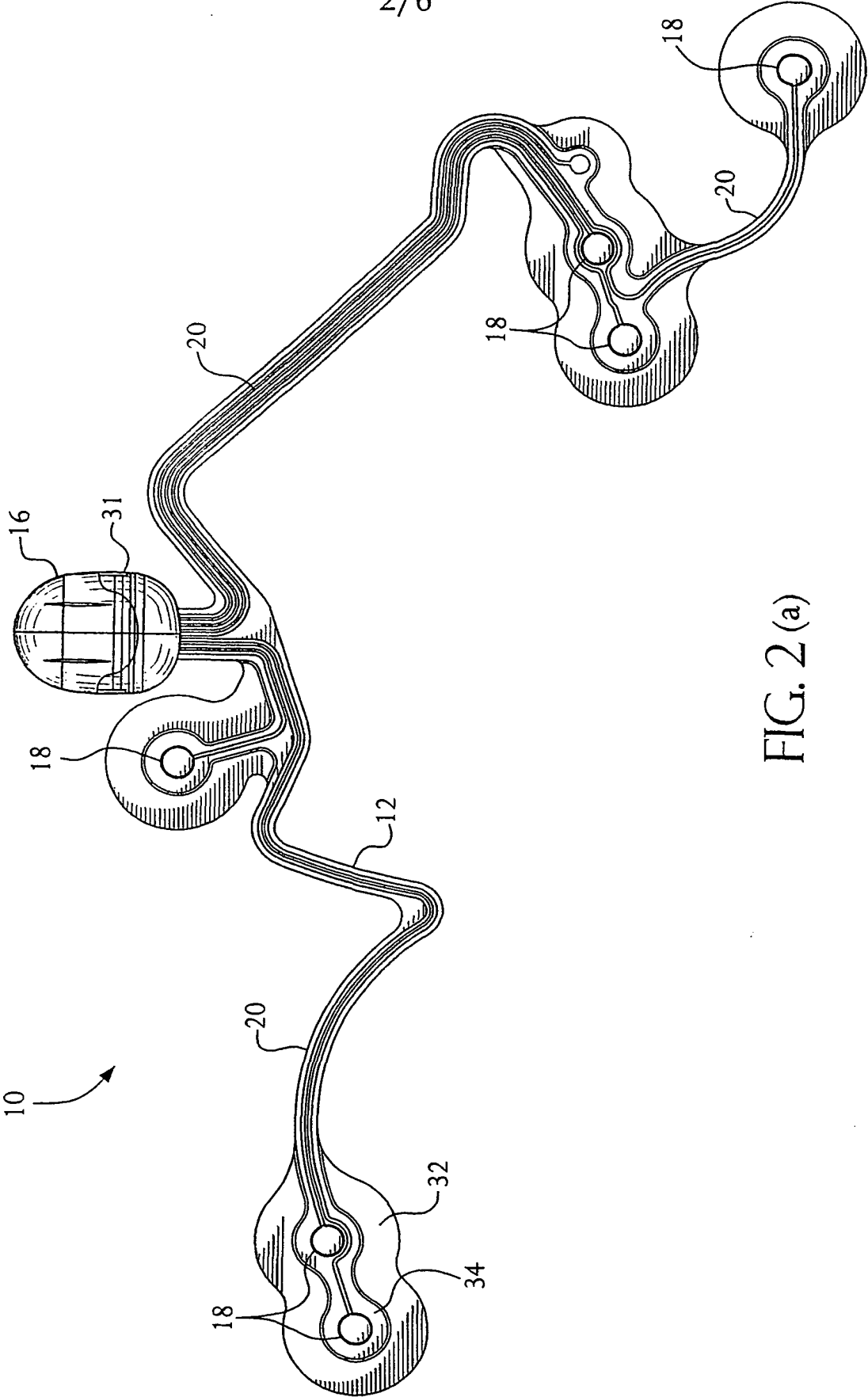


FIG. 2(a)

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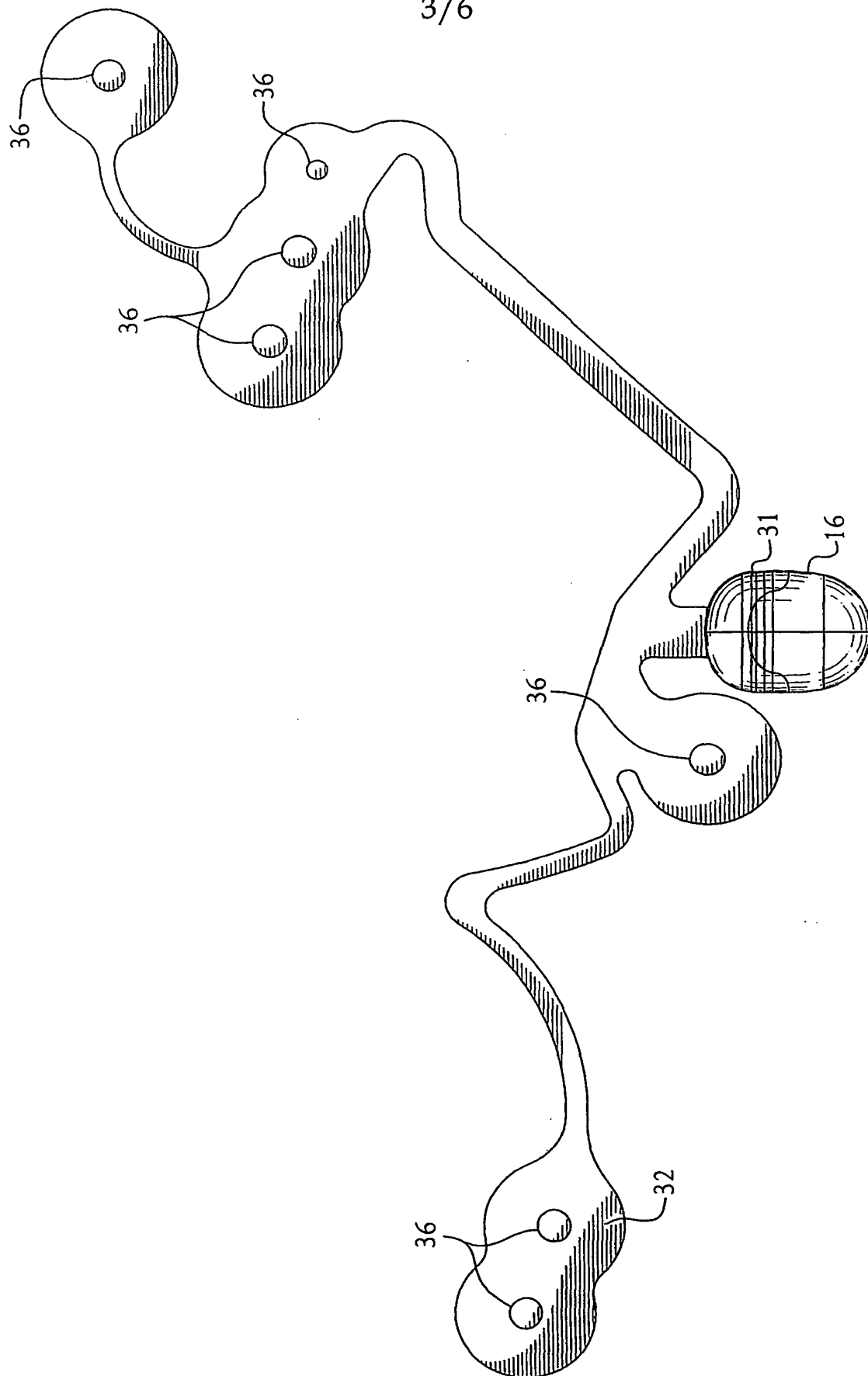


FIG. 2(b)

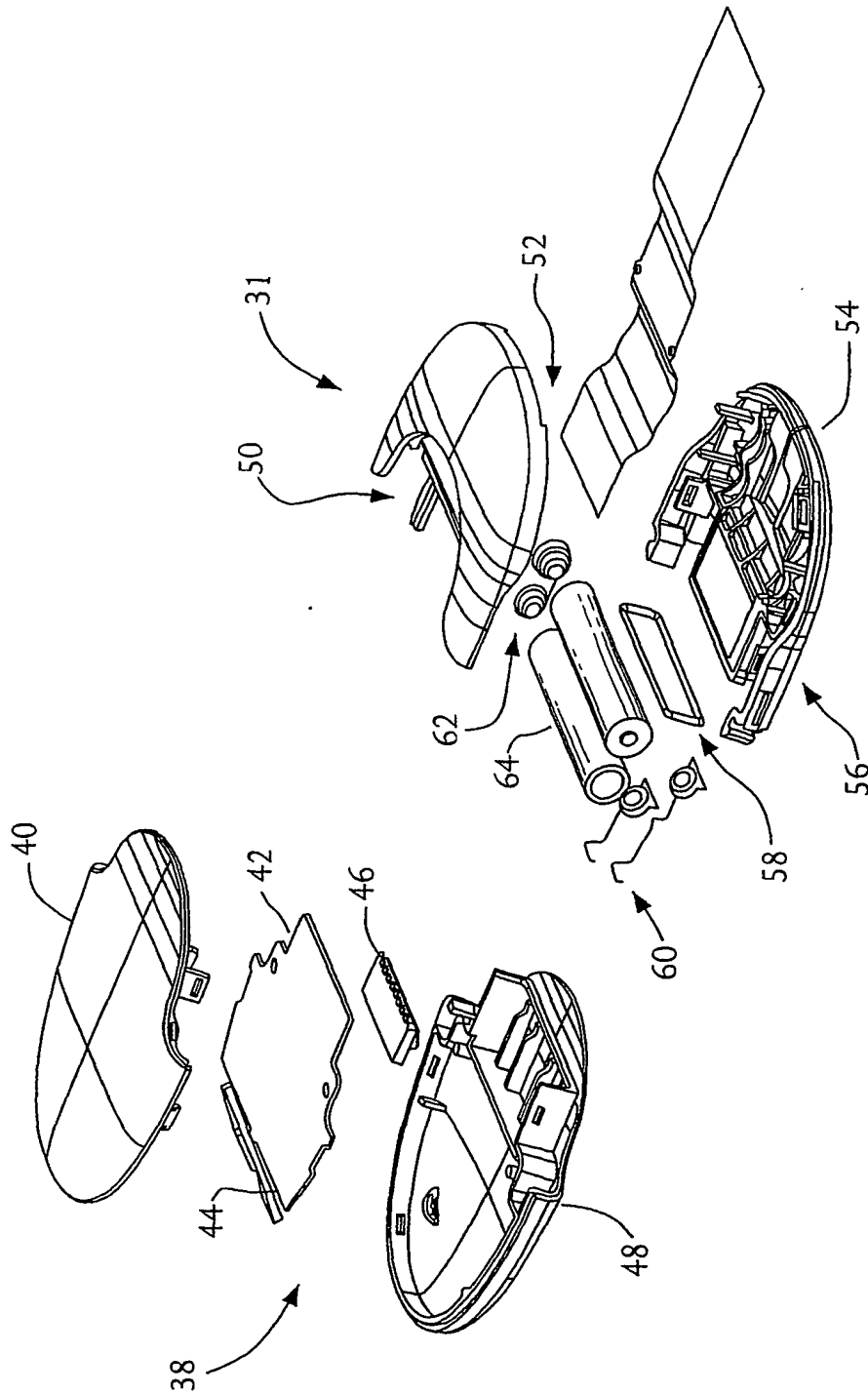


FIG. 3

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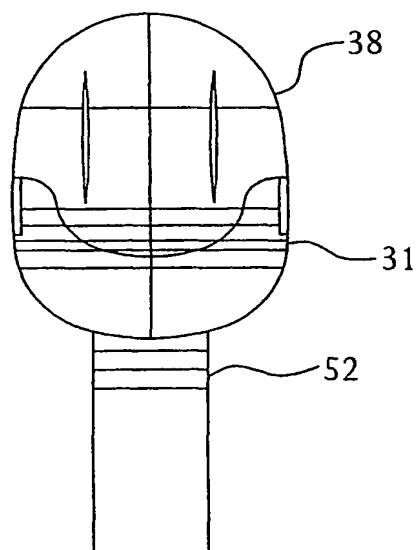


FIG. 4

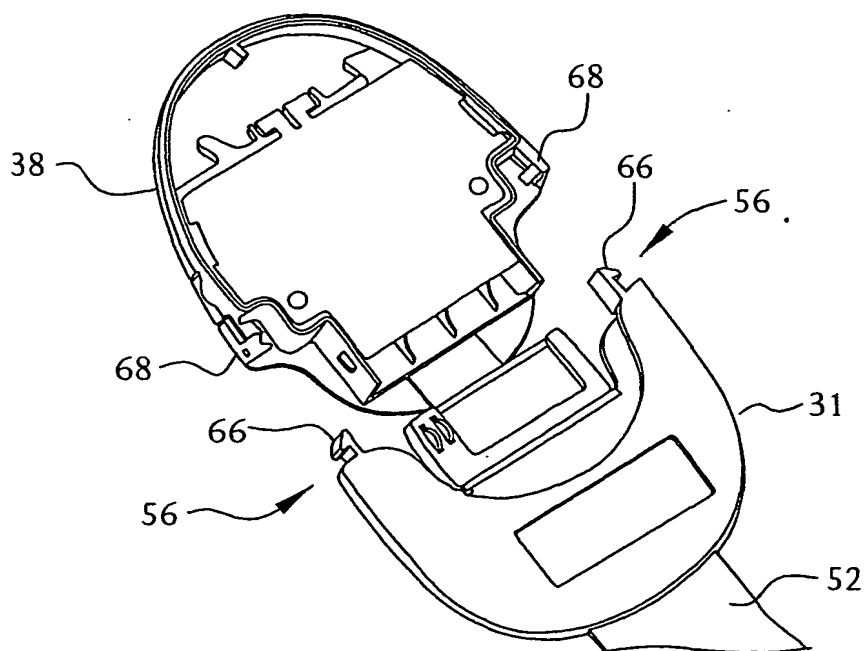


FIG. 5

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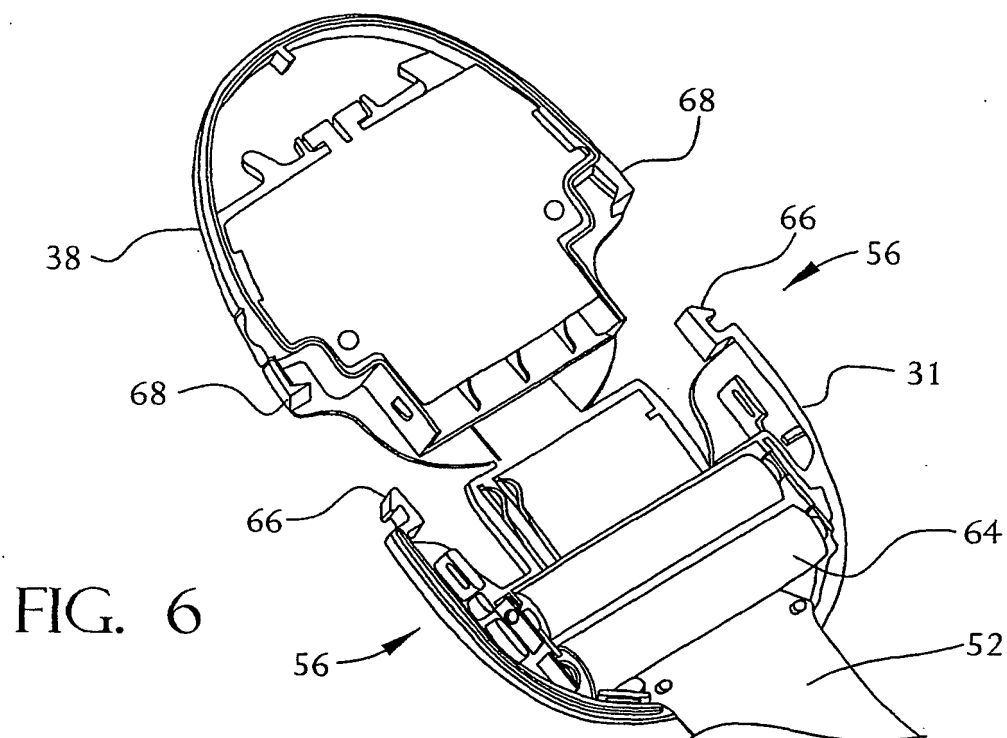


FIG. 6

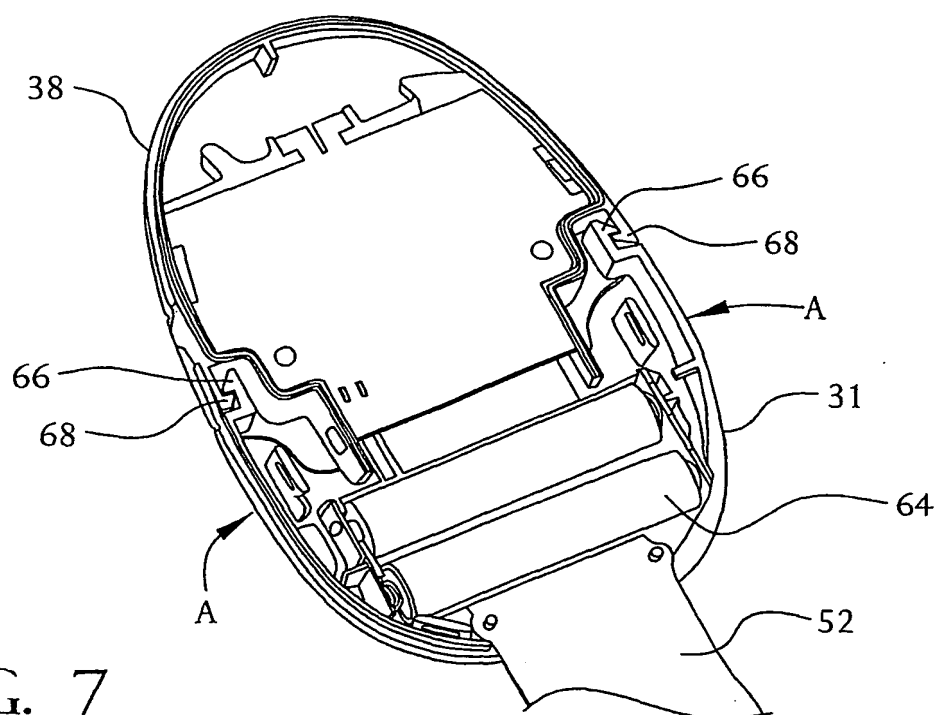


FIG. 7

INTERNATIONAL SEARCH REPORT

Inte Application No

PCT/GB 01/04078

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61B5/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, PAJ, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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Y	US 5 678 562 A (SELLERS CRAIG S) 21 October 1997 (1997-10-21) claim 24; figures 2B,2C	1
A	EP 0 612 498 A (OHTAKE TUTOMU) 31 August 1994 (1994-08-31) abstract; figure 1	1
A	US 5 637 417 A (ENGMARK DAVID B ET AL) 10 June 1997 (1997-06-10)	

☐ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents :

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- *&* document member of the same patent family

Date of the actual completion of the international search

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07/02/2002

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INTERNATIONAL SEARCH REPORT

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PCT/GB 01/04078

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